

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims of this application:

Listing of Claims:

1. (Currently Amended) An oral solid pharmaceutical dosage form comprising an extended release (ER) tablet, wherein said ER tablet ~~comprises~~ consists essentially of:
 - a. an effective amount of a macrolide antibiotic selected from clarithromycin, azithromycin, erythromycin or an erythromycin derivative;
 - b. from about 2% to about 40% w/w of one or more pharmaceutically acceptable water soluble excipients selected from the group consisting of fillers, tableting aids, glidants and lubricants;
 - c. ~~one or more tableting aids~~ a binder selected from the group consisting of polyvinyl pyrrolidone, hydroxypropyl methylcellulose having an average viscosity of 3 to 15 cps, hydroxypropylcellulose having an average viscosity of 3 to 15 cps and mixtures thereof;
 - d. ~~wherein the dosage form does not contain a dissolution rate controlling polymer~~ optionally, a film coating on said ER tablet; and
 - e. wherein said tablet when tested in a USP Apparatus 2 at 50 rpm using 900 mL 0.1M sodium acetate buffer (pH=5.0) at 37°C exhibits a dissolution profile substantially corresponding to the following pattern:

not more than 35% of the total antibiotic is released in 2 hours;

about 30-60% of the total antibiotic is released in 4 hours;

about 50-90% of the total antibiotic is released in 8 hours; and

not less than 70% of the total antibiotic is released in 12 hours.

2. (Original) A pharmaceutical dosage form as defined in claim 1, wherein said dissolution profile substantially corresponds to the following pattern:

not more than 30% of the total antibiotic is released in 2 hours;

about 30-50% of the total antibiotic is released in 4 hours;

about 60-85% of the total antibiotic is released in 8 hours; and

not less than 85% of the total antibiotic is released in 12 hours.

3. (Currently amended) A pharmaceutical dosage form as defined in claim 2, wherein said tablet core is prepared by (1) granulating clarithromycin, at a concentration of from about 62% to about 90% w/w based on the total tablet weight with a pharmaceutically acceptable filler selected from the group consisting of lactose, mannitol, and microcrystalline cellulose, using an aqueous solution of a ~~hydrophilic~~ the binder which is optionally acidified with hydrochloric acid to a normality ranging from about 0.005 to about 0.05, (2) blending said granules with a tableting aid selected from the group consisting of magnesium stearate, fine colloidal silicon dioxide, talc, microcrystalline cellulose, lactose and mixture thereof, and (3) compressing the blend into 500 mg or 1000 mg tablets in the weight range of about 575 - 750 mg and 1120-1500 mg, respectively.

4. (Previously presented) A pharmaceutical dosage form as defined in claim 3 wherein the pharmaceutically acceptable filler in the granulation includes lactose and said filler is present at a concentration of from about 5% to about 35% w/w.

5. (Currently amended) A pharmaceutical dosage form as defined in claim 4 wherein said ~~hydrophilic binder is selected from the group consisting of polyvinylpyrrolidone, hydroxypropylmethylcellulose, hydroxypropylcellulose, cornstarch, and dextran~~ is present for granulation at a concentration of from about 1% to about 4% w/w based on the total tablet weight, ~~added as an aqueous solution of a mineral acid.~~

6. (Original) A pharmaceutical dosage form as defined in claim 3 wherein said tableting aid includes lactose blended at a concentration of about 1-5 % by weight of total tablet weight.

7. (Original) A pharmaceutical dosage form as defined in claim 3 wherein said tableting aid includes microcrystalline cellulose blended at a concentration of about 1-4 % by weight for a total polymer content of not more than 5% by weight of the tablet.

8. (Previously presented) A pharmaceutical dosage form as defined in claim 3 wherein said tableting aid is magnesium stearate alone or in combination with talc externally blended at a total concentration of from about 1.0 % to about 10 % by weight.

9. (Previously presented) A pharmaceutical dosage form as defined in claim 3 wherein said tableting aid is colloidal silicon dioxide externally blended at a concentration of about 0.1-0.5 % by weight of total tablet weight.

10-12. (Cancelled)

13. (Previously presented) A pharmaceutical dosage form as defined in claim 3 wherein the tablet core is provided with a film coat.

14. (Previously presented) A pharmaceutical dosage form as defined in claim 2, wherein said tablet core is prepared by (1) granulating the macrolide antibiotic, at a concentration of from about 62% to about 90% w/w based on the total tablet weight with a pharmaceutically acceptable filler selected from the group consisting of lactose, mannitol, and microcrystalline cellulose, using an aqueous solution of a hydrophilic binder which is optionally acidified with hydrochloric acid to a normality ranging from about 0.005 to about 0.05, (2) blending said granules with a tableting aid selected from the group consisting of magnesium stearate, fine colloidal silicon dioxide, talc, microcrystalline cellulose, lactose and mixture thereof, and (3) compressing the blend into 500 mg or 1000 mg tablets in the weight range of about 575 - 750 mg and 1120-1500 mg, respectively.

15. (New) A pharmaceutical dosage form as defined in claim 1 wherein said binder comprises polyvinyl pyrrolidone.

16. (New) An oral solid pharmaceutical dosage form comprising an extended release (ER) tablet, wherein said ER tablet consists essentially of:

- a. from about 62% to about 90% w/w based on the total tablet weight of a macrobide antibiotic selected from the group consisting of clarithromycin, azithromycin, erythromycin and an erythromycin derivative;
- b. a binder selected from the group consisting of polyvinyl pyrrolidone, hydroxypropyl methylcellulose having an average viscosity of 3 to 15 cps, hydroxypropylcellulose having an average viscosity of 3 to 15 cps and mixtures thereof;
- c. a pharmaceutically acceptable filler selected from the group consisting of lactose, mannitol, microcrystalline cellulose and mixtures thereof;
- d. a lubricant selected from the group consisting of magnesium stearate, talc, calcium stearate, stearic acid and mixtures thereof;
- e. optionally a glidant; and
- f. optionally a film coating on said ER tablet;

wherein said tablet when tested in a USP Apparatus 2 at 50 rpm using 900 mL 0.1M sodium acetate buffer (pH=5.0) at 37°C exhibits a dissolution profile substantially corresponding to the following pattern:

- not more than 35% of the total antibiotic is released in 2 hours;
- about 30-60% of the total antibiotic is released in 4 hours;
- about 50-90% of the total antibiotic is released in 8 hours; and
- not less than 70% of the total antibiotic is released in 12 hours.

17. (New) The pharmaceutical dosage form of claim 16 wherein said macrolide antibiotic comprises clarithromycin.

18. (New) The pharmaceutical dosage form of claim 17 wherein said binder comprises polyvinylpyrrolidone.
19. (New) The pharmaceutical dosage form of claim 18 wherein said filler comprises lactose.
20. (New) The pharmaceutical dosage form of claim 16 wherein said ER tablet consists essentially of clarithromycin, polyvinyl pyrrolidone, lactose, magnesium stearate and talc.
21. (New) The pharmaceutical dosage form of claim 19 wherein said ER tablet consists essentially of clarithromycin, polyvinylpyrrolidone, the filler and the lubricant.
22. (New) The pharmaceutical dosage form of claim 16 wherein the binder is present at a concentration of about 0.5 to 5 wt%.
23. (New) The pharmaceutical dosage form of claim 16 wherein the total polymer content of the tablet is not more than 5% by weight.